This application claims priority to U.S. Provisional Application 60/152,240 filed on September 3, 1999, and U.S. Provisional Application 60/158,245 filed on October 8, 1999, and is a continuation of U.S. Patent Application Serial No. 09/653,861, filed on September 1, 2000, now abandoned.

SUPPORT FOR THE AMENDMENTS

Applicants have amended page 1 of the specification to recite the claim of priority to U.S. Patent Application Serial No. 09/653,861, filed on September 1, 2000, now abandoned. Support for this amendment can be found in the Request for Priority filed with the application on February 14, 2002, and on the Official Filing Receipt for the present application.

No new matter has been added. Claims 1-14 remain active in this application.

REMARKS

Present Claims 1-3 relate L-carnitine having a particle size such that it substantially passes through a 100 USBS mesh sieve (hereinafter referred to as "ultrafine L-carnitine"). Present Claims 4-6 relate to methods for preparing such ultrafine L-carnitine. Present Claims 7-11 relate to compositions which contain such ultrafine L-carnitine. Present Claims 12-14 relate to methods of treatment using such ultrafine L-carnitine.

The inventor has discovered that the presently claimed ultrafine L-carnitine provides a number of advantages as compared to conventional L-carnitine. The cited references provide no teaching which would suggest the presently claimed ultrafine L-carnitine, or the various claimed compositions and methods. Accordingly, these references cannot affect the patentability of the present claims.

The rejection of Claims 1-14 under 35 U.S.C. § 103(a) in view of U.S. Patent No. 4,602,039 (Cavazza I) in view of U.S. Patent no. 6,063,820 (Cavassa II) is respectfully traversed.

Cavazza I is discussed on page 5, lines 14-22, of the specification. Thus, as explained in the specification, the undisputed difference between the L-carnitine of Cavazza I and the presently claimed ultrafine L-carnitine is that the presently claimed ultrafine L-carnitine and salts thereof have a particle sufficiently small that substantially all of it passes through a 100, or even a 150 or 200, United States Bureau of Standards (USBS) mesh screen. In contrast, the L-carnitine and salts thereof perpared by the methods described in Cavazza I have a particle size such that more than 10% by weight of the L-carnitine is retained by a 50 mesh sieve and more than 40% by weight is retained by a 100 mesh sieve.

Applicant submits that the presently claimed ultrafine L-carnitine affords a number of advantages which could not have been expected based on the teachings of the cited references. Moreover, these advantages are discussed in the present specification itself. For example, on page 1, in the "Field of the Invention," it is disclosed:

> In particular, the present invention relates to L-carnitine and salts thereof which exist in the form of ultra-fine particles. The present ultra-fine L-carnitine is capable of being uniformly blended with fine particles of other raw materials, while maintaining its own discrete shape. ***The overall fineness of the present ultra-fine L-carnitine makes it ideal for blending with oil-based raw materials with which conventional bulk carnitine is not entirely miscible.***

Similarly, on page 2, second and third paragraphs, of the present specification, in the "Description of the Background," it is disclosed:

It is also desired to prepare compositions which contain L-carnitine and one or more other ingredients with which bulk L-carnitine is not miscible, e.g., oil-based raw materials. It is further desired to reduce the hygroscopicity of L-carnitine.

* * *

There also remains a need for forms of L-carnitine and salts thereof which can be easily formulated with other ingredients with which bulk L-carnitine is not miscible, e.g., oil-based raw materials. There also remains a need for forms of L-carnitine and salts thereof which exhibit a decreased hygroscopicity.

Moreover, on page 5, it is disclosed:

The ultra-fine L-carnitine and salts thereof of the present invention has a particle sufficiently small that substantially all of it passes through a 100 United State [*sic*, States] Bureau of Standards (USBS) mesh screen. In a preferred embodiment, the ultra-fine L-carnitine and salts thereof of the present invention has a particle sufficiently small that substantially all of it passes through a 150 USBS mesh screen. In a particularly preferred embodiment, the ultra-fine L-carnitine and salts thereof of the present invention has a particle sufficiently small that substantially all of it passes through a 200 USBS mesh screen.

The ultra-fine L-carnitine and salts thereof of the present invention may be prepared by reducing the size of conventional L-carnitine and salts thereof and selecting the appropriately sized particles by sieving. Currently, L-carnitine and salts thereof are conveinently prepared by the methods described in U.S. Patent Nos. 4,254,053; ***4,602,039***; and 5,412,113 and European Patent Application EP-A-0150688, which are incorporated herein by reference. ***Such procedures typically yield L-carnitine having a size of such that greater than 10% by weight of the L-carnitine is retained by a 50 mesh sieve and more than 40% by weight is retained by a 100 mesh sieve.***

Thus, at the time the present invention was made there was a need for preparing compositions containing L-carnitine and one or more other ingredients with which bulk L-

carnitine is not miscible, (*e.g.*, oil-based raw materials). Moreover, at the time the present invention was made there was also a need for reducing the hygroscopicity of L-carnitine.

In other words, even though the L-carnitine (for example the fumarate salt) prepared according to Cavazza I demonstrates an improvement in handling abilities, for example for tabletting, over previous forms of carnitine, the L-carnitine prepared according to Cavazza I still possesses a particle size and bulk density that is less than ideal for certain other applications, such as containment within hard and soft geltain capsules. For this reason, many transformers rejected its use for hard and soft gel applications, choosing to remain with tablets.

It was not obvious to reduce the size of the particles as disclosed in the present application, since this was felt unworkable. Specifically, carnitine in any form is seldom a candidate for particle size reduction, because the frictional heat generated during the particle size reduction process may induce the humid state relative to the ambient air temperature and thereby produce sticking.

For these reasons, the presently claimed ultrafine L-carnitine is not obvious in light of Cavazza I.

Applicant submits that Cavazza II cannot cure the basic deficiencies of Cavazza I for the following reasons. Cavazza II discloses carnitine and salts thereof in combination with other active ingredients. However, the L-carnitine used in Cavazza II is produced using the method described in Cavazza I and, thus, has the characteristics of that of Cavazza I.

However, as explained above, only by using ultrafine L-carnitine in combination with omega-3 fatty acids in fish oil or coenzyme Q10, or alpha lipoic acid, is it possible to obtain

an easily workable mixture. The same good results would not have been obtained using L-carnitine produced according to Cavazza I.

Cavazza II does not mention or suggest the use of the ultrafine L-carnitine according to the present claims. For these reasons Cavazza II alone, or even in combination with Cavazza I, can not render the present invention obvious.

Accordingly, the rejection should be withdrawn.

Applicant acknowledges that Examiner's request that the specification be amended to recite the claim of priority to the parent application. In this regard, Applicant notes that such an amendment was requested on the Utility Patent Application Transmittal filed with the present application on February 14, 2002. In any event, Applicant is complying with the Examiner's request in the present amendment.

Applicant submits that the application is now in condition for allowance, and early notification of such action is earnestly solicited.

Respectfully submitted,

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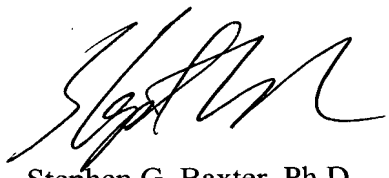

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MARKED-UP COPY OF AMENDMENT FILED HEREWITH

IN THE SPECIFICATION

Please amend the specification as follows.

Page 1, lines 6-8, please amend as follows:

--This application claims priority to U.S. Provisional Application 60/152,240 filed on September 3, 1999, and U.S. Provisional Application 60/158,245 filed on October 8, 1999, and is a continuation of U.S. Patent Application Serial No. 09/653,861, filed on September 1, 2000, now abandoned.--